October 23, 2020

Tammy Dean
Manager of Regulatory Affairs
Roche Diagnostics
9115 Hague Rd PO Box 50416
Indianapolis, IN 46250

Re: EUA200514/S003
Device Name (Authorized): Elecsys Anti-SARS-CoV-2
Authorization Date: May 2, 2020
Supplement Received: September 24, 2020

Dear Ms. Tammy Dean:

This is to notify you that your request to update the Fact Sheet for Healthcare Providers and the Instructions for Use (IFU) of the Elecsys Anti-SARS-CoV-2, to include a limitation, is granted. Upon review, for the Elecsys Anti-SARS-CoV-2, we concur with the additional limitation to the package insert: "*A positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.*" We also concur with the additional statement to the Fact Sheet for Health Care Providers: "*Due to the risk of false positive results, confirmation of positive results should be considered – using a second, different antibody assay that detects the same type of antibodies.*" for the Elecsys Anti-SARS-CoV-2. FDA also made minor updates to the IFU, the Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients to reflect more recent authorizations.

By submitting this revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Elecsys Anti-SARS-CoV-2 issued on May 2, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
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